Department of Health and Human Services
Centers for Disease Control and Prevention
Division of Select Agents and Toxins
Atlanta, GA

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Agriculture Select Agent Services
Riverdale, MD

June 7, 2018

(b)(6); (b)(3):42 U.S.C. § 262a(h)(1)(E) (Responsible Official)
U.S. Army Medical Research Institute of Infectious Diseases
1425 Porter Street
Fort Detrick, MD 21702
(b)(6); (b)(3):42 U.S.C. § 262a(h)(1)(E)

Subject: Request to Continue Work Stoppage Involving Select Agents and Toxins at U.S. Army Medical Research Institute of Infectious Disease (USAMRIID)

On May 30, 2018, USAMRIID notified the Federal Select Agent Program (FSAP) that it had ceased work with select agents and toxins in all Biosafety Level (BSL)-3 and BSL-4 laboratories. USAMRIID reported that the work stoppage was based on the following incident: steam sterilization plant (SSP) upper storage tanks being filled beyond capacity and backed-up into a vent pipe that leaked chemically treated effluent from USAMRIID laboratories onto the grass outside the tank containment area. USAMRIID reported that it had cordoned off the area and was conducting tests to determine whether the release of chemically treated effluent from the BSL-3 and BSL-4 laboratories posed a risk to public health and safety as well as animal health and safety. USAMRIID reported to FSAP that the initial environmental test results demonstrate that there is currently no risk to public health and safety as well as animal health and safety.

Based on USAMRIID's May 30, 2018 notification and the results of an inspection of USAMRIID conducted by the Federal Select Agent Program (FSAP) on May 21-22, 2018, FSAP requests USAMRIID to continue its work stoppage involving select agents and toxins in all registered laboratory areas where laboratory effluent is discharged into the SSP; and that the select agents and toxins connected to this work stoppage be stored to prevent theft, loss, or release until such time as the following concerns identified during the May 21-22, 2018 inspection have been addressed:

- USAMRIID's failure to implement biosafety procedures commensurate with the risk of the select agents and toxins used in USAMRIID's BSL-3 and BSL-4 laboratories. Specifically, validated chemical treatment procedures for effluent discharged from BSL-3 and BSL-4 laboratories supported by the SSP as written in the USAMRIID biosafety plan were not followed by laboratory personnel. [Section 12(a)]

- USAMRIID's failure to implement containment procedures sufficient to contain select agents or toxins contained in effluent generated by USAMRIID's BSL-3 and BSL-4 laboratories. [Section 12(b)]

FSAP requests:

1. Documentation that USAMRIID has implemented validated chemical treatment procedures for effluent discharged from BSL-3 and BSL-4 laboratories supported by the SSP; and

2. USAMRIID's plan to mitigate and clean up the effluent spills to prevent risk to public health and

safety; as well as animal health and safety. Please provide copies of environmental testing that has been conducted and will be conducted for the affected area.

Sincerely,

Samuel S. Edwin

Samuel Edwin, Ph.D.
Director, Division of Select Agents and Toxins
Department of Health and Human Services
Centers for Disease Control & Prevention

Keith Wiggins, DVM
Acting Director, Agriculture Select Agent Services
Animal & Plant Health Inspection Service
United States Department of Agriculture

Department of Health and Human Services
Centers for Disease Control and Prevention
Division of Select Agents and Toxins
Atlanta, GA

July 9, 2019

Colonel Gary A. Wheeler
Commander
U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)
1425 Porter Street
Fort Detrick, MD 21702

Subject: USAMRIID Biosafety Lapses

Dear Colonel Wheeler:

The Federal Select Agent Program (FSAP) is jointly comprised of the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) and the Animal and Plant Health Inspection Service (APHIS), Agriculture Select Agent Services (AgSAS). Pursuant to federal select agents and toxins regulations (7 CFR part 331, 9 CFR part 121, 42 CFR part 73), FSAP has oversight responsibility for all entities that possess, use, or transfer biological agents and toxins that have the potential to pose a severe threat to public health and safety, animal and plant health and animal and plant products (select agents and toxins). As part of its oversight responsibility, FSAP regularly inspects entities to evaluate whether they meet the regulatory requirements set forth in the select agents and toxins regulations. The above referenced regulations and supporting guidance may be found at http://www.selectagents.gov.

The purpose of this letter to advise you that USAMRIID is displaying an ongoing pattern of unsafe biosafety practices that can best be described as deviations from nationally recognized biosafety standards as well as USAMRIID's own biosafety plan observed during the last FSAP inspection of your facility conducted during June 3-7, 2019. Specifically:

(b)(3):42 U.S.C. § 262a(h)(1)(E)

- An individual was observed partially entering Animal Biosafety Level 3 (ABSL-3) Room [redacted] multiple times on March 25, 2019 without the required respiratory protection while the room was being used to perform procedures with a (b)(3):42 U.S.C. § 262a(h)(1)(E) infected non-human primate (NHP) on a necropsy table and other infected NHPs were housed in open caging. USAMRIID's biosafety plan requires the use of a powered air purifying respirator (PAPR) in animal rooms when infected animals are present.
- USAMRIID laboratorians have been observed not wearing appropriate personal protective equipment (PPE) in containment suites prescribed by the USAMRIID biosafety plan.
- USAMRIID laboratorians were observed deviating from USAMRIID standard operating procedures (SOPs) by propping open ABSL-3 doors, increasing the risk of contaminated air escaping an ABSL-3 laboratory and exposing USAMRIID laboratorians not wearing respiratory protection outside of ABSL-3 containment.
- USAMRIID laboratorians were observed using a contaminated downdraft table as a prop for a PAPR blower while exiting an ABSL-3 room. This created a potential fomite/exposure route because the PAPR blower was not decontaminated per USAMRIID SOP prior to its removal from the laboratory.
- USAMRIID laboratorians informed FSAP inspectors that they deviated from USAMRIID used animal cage decontamination SOPs because they believed that it did not really matter when the cages were decontaminated.
- USAMRIID laboratorians were unable to consistently describe to FSAP inspectors the USAMRIID PPE doffing procedures for exiting the Biosafety Level 3 (BSL-3)/ABSL-3 containment suites.

- Since 2018, USAMRIID has submitted (b)(3):42 U.S.C. § 262a(h)(1)(D)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

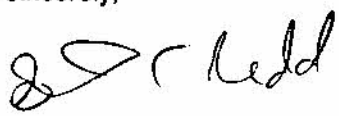
(b)(3):42 U.S.C. § 262a(h)(1)(E)

FSAP believes that the limitations caused by the failures of the USAMRIID effluent decontamination system (EDS) exacerbate the procedural biosafety failures at USAMRIID. It is our understanding that the Fort Detrick medical waste incinerator is not operational. USAMRIID has associated multiple reports of releases of select agents with failures at the steam sterilization plant in building [redacted] and the chemical EDS associated with building [redacted] Additionally, FSAP believes that attempts by USAMRIID to work around facility limitations has created additional biosafety issues and facility failure points that compromise the safety of continued operations at USAMRIID.

The FSAP is bringing what it believes to be a serious situation to your attention based on the FSAP concern that a systemic and sustained unsafe biosafety culture has developed at USAMRIID that requires immediate command attention.

Please contact Dr. Samuel Edwin, DSAT Director at 404-718-2001 if you have questions regarding this correspondence.

Sincerely,



Stephen C. Redd, M.D.
RADM USPHS
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Department of Health and Human Services

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